

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Advisory Committee (PCNS) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

May 24, 2012

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Glendolynn S. Johnson, Pharm.D.

Division of Advisory Committee & Consultant Management

Office of Executive Programs, CDER, FDA

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Jeffrey A. Cohen, M.D.

Professor, Neurology

Dartmouth Medical School

Section Chief, Neurology

Director, Clinical Neurophysiology Fellowship

Dartmouth Hitchcock Medical Center

Lebanon, New Hampshire

Samuel A. Frank, M.D.

(Consumer Representative)

Associate Professor of Neurology

Boston University School of Medicine

Boston, Massachusetts

Nathan B. Fountain, M.D.

(Acting Chairperson)

Professor, Department of Neurology

Director, FE Dreifuss Comprehensive Epilepsy

Program

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Charlottesville, Virginia

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Staff Physician

Dallas Veterans Affairs (VA) Medical Center

Clinical Associate Professor of Neurology

University of Texas Southwestern Medical School

Dallas, Texas

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Lynn Kramer, M.D., FAAN *(Industry Representative)*

President, Neuroscience PCU

Eisai, Inc.

Wood Cliff Lake, New Jersey

TEMPORARY MEMBERS (Voting)

Emilia Bagiella, Ph.D.

Professor of Biostatistics

Department of Health Evidence and Policy

Mount Sinai School of Medicine

New York, New York

Vinay Chaudhry, M.D.

Professor Neurology

Director Neurology Outpatient Center

Johns Hopkins University School of Medicine

Baltimore, Maryland

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MEETING ROSTER (cont.)

Robert R. Clancy, M.D.

Professor of Neurology and Pediatrics
The University of Pennsylvania School of Medicine
The Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

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Department of Health Sciences Research
Division of Epidemiology
Mayo Clinic
Rochester, Minnesota

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Director, Neuromuscular Center and EMG Lab
Boston VA Health Care System
Director, Neuromuscular Rehab Clinic
Brigham and Women's Hospital
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Assistant in Pathology (Neuropathology)
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Boston, Massachusetts

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Director, USF Neuroscience Collaborative
University of South Florida
Tampa, Florida

David C. Preston, M.D.

Vice Chairman of Neurology
Professor of Neurology
Program Director, Neurology Residency
University Hospitals - Case Medical Center
Cleveland, Ohio

Tiffany House

(Patient Representative)
San Antonio, Texas

Paul B. Rosenberg, M.D.

Associate Professor of Psychiatry and Behavioral
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Division of Geriatric Psychiatry and
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John Hopkins University School of Medicine
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Professor of Neurology and Physical Medicine and
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Unit Chief, Neuromuscular Division
Department of Neurology
Director, EMG Laboratory
University of Rochester Medical Center
Rochester, New York

Jeremy Shefner, M.D., Ph.D.

Professor and Chair of Neurology
State University of New York (SUNY) Upstate
Medical University
Syracuse, New York

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Ashok Verma, M.D., D.M., M.B.A.

Professor

Medical Director

Kessenich Family MDA-ALS Center and Clinics

University of Miami Miller School of Medicine

Miami, Florida

FDA PARTICIPANTS (Non-Voting)

Ellis Unger, M.D.

Acting Director

Office of Drug Evaluation I (ODE-I)

Office of New Drugs (OND), CDER, FDA

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Director, Division of Neurology Products (DNP)

ODE-I, OND, CDER, FDA

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Clinical Team Leader, DNP

ODE-I, OND, CDER, FDA

Devanand Jillapalli, M.D.

Medical Officer, DNP

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Julia Luan, Ph.D.

Mathematical Statistician

Division of Biostatistics 1, Office of Biostatistics

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